SETTLEMENT AGREEMENT
BETWEEN
MISSOURI BOARD OF PHARMACY
AND
CHARITON HEALTH SYSTEMS, INC.
D/B/A COMMUNITY MEDICAL EQUIPMENT

Chariton Health Systems, Inc. d/b/a Community Medical Equipment ("Community Medical Equipment"), and the Missouri Board of Pharmacy, ("Board"), enter into this Settlement Agreement for the purpose of resolving the question of whether Community Medical Equipment's license as a drug distributor, no. 2004013278, will be subject to discipline. Pursuant to § 536.060, RSMo, 2000,[1] the parties hereto waive the right to a hearing by the Administrative Hearing Commission of the State of Missouri and, additionally, the right to a disciplinary hearing before the Board under § 621.110, RSMo, Cum. Supp. 2010. The Board and Community Medical Equipment jointly stipulate and agree that a final disposition of this matter may be effectuated as described below pursuant to § 621.045, RSMo, Cum. Supp. 2010.

Community Medical Equipment acknowledges that it understands the various rights and privileges afforded it by law, including the right to a hearing of the charges against it; the right to appear and be represented by legal counsel; the right to have all charges proven upon the record by competent and substantial evidence; the right to cross-examine any witnesses appearing against it at the hearing; the right to present evidence on its behalf at the hearing; the right to a decision upon the record of the hearing by a fair and impartial administrative hearing commissioner concerning the charges

[1] All statutory citations are to the 2000 Revised Statutes of Missouri unless otherwise noted.

pending against it; the right to a ruling on questions of law by the Administrative Hearing Commission; the right to a disciplinary hearing before the Board at which time Community Medical Equipment may present evidence in mitigation of discipline; the right to a claim for attorney fees and expenses; and the right to obtain judicial review of the decisions of the Administrative Hearing Commission and the Board.

Being aware of these rights provided to it by law, Community Medical Equipment knowingly and voluntarily waives each and every one of these rights and freely enters into this Settlement Agreement and agrees to abide by the terms of this document as they pertain to it.

Community Medical Equipment acknowledges that it has received a copy of documents that were the basis upon which the Board determined there was cause for discipline, along with citations to law and/or regulations the Board believes were violated. Community Medical Equipment stipulates that the factual allegations contained in this Settlement Agreement are true and stipulates with the Board that Community Medical Equipment's license as a drug distributor, no. 2004013278, is subject to disciplinary action by the Board in accordance with the relevant provisions of Chapters 621 and 338, RSMo, as amended.

The parties stipulate and agree that the disciplinary order agreed to by the Board and Community Medical Equipment in Part II herein is based only on the agreement set out in Part I herein. Community Medical Equipment understands that the Board may take further disciplinary action against it based on facts or conduct not specifically

mentioned in this document that are either now known to the Board or may be discovered.

I.
Joint Stipulation of Facts and Conclusions of Law

Based upon the foregoing, the Board and Community Medical Equipment herein jointly stipulate to the following:

1. Petitioner, the Board, is an agency of the State of Missouri created pursuant to § 338.140, RSMo, for the purpose of executing and enforcing the provisions of Chapter 338, RSMo, as amended.

2. Respondent, Chariton Health Systems, Inc. d/b/a Community Medical Equipment ("Community Medical Equipment") is located at 107 Market Street, Glasgow, Missouri.

3. Community Medical Equipment is licensed as a wholesale drug distributor, license no. 2004013278.

4. Community Medical Equipment's wholesale drug distributor license is current and active at all times relevant herein.

5. Section 338.055.2, RSMo, Cum. Supp. 2010, states in pertinent part:

> 2. The board may cause a complaint to be filed with the administrative hearing commission as provided by chapter 621, RSMo, against any holder of any certificate of registration or authority, permit or license required by this chapter or any person who has failed to renew or has surrendered his certificate of registration or authority, permit or license for any one or any combination of the following causes:
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> . . . .

(5) Incompetence, misconduct, gross negligence, fraud, misrepresentation or dishonesty in the performance of the functions or duties of any profession licensed or regulated by this chapter;

(6) Violation of, or assisting or enabling any person to violate, any provision of this chapter, or of any lawful rule or regulation adopted pursuant to this chapter;

. . . .

(13) Violation of any professional trust or confidence;

. . . .

(15) Violation of the drug laws or rules and regulations of this state, any other state or the federal government;

6. In July 2004 and August 2005, a Board inspector conducted an inspection of Community Medical Equipment's facility and cited it for not having written policies and procedures in place for monitoring/reporting losses or thefts of medical gases.

7. In May 2007, a Board inspector conducted an inspection of Community Medical Equipment's facility and cited it for not having a manager-in-charge ("MIC") at the time present during normal business hours; there was no documentation of scale certification; nitrous oxide was stored on-site, but not under lock and key; there was no alarm system; the authorized personnel list was incorrect; there were incorrect fill temperatures recorded on the compressed cylinder batch logs; the label inventory on hand did not match the reconciliation logs; and there were not written policies and procedure in place for monitoring/reporting losses or thefts of medical gases.

8. On or about February 10, 2009, a Board inspector conducted an inspection of Community Medical Equipment's facility, which revealed:

a) Greg Spieser, the MIC at that time, was not present during normal business hours;

b) There was no documentation of current gauge certification;

c) There was no review of the Servomex calibration by the Quality Control Unit, as required by company policy, on the following dates: January 16, 2009; January 23, 2009; January 30, 2009; February 2, 2009, February 4, 2009; February 6, 2009; and February 9, 2009; and

d) Community Medical Equipment was also instructed that they needed to verify the accuracy of the thermometer used for transfilling O_2.

9. On or about March 11, 2009, the Board inspector conducted a follow-up inspection which revealed:

a) Greg Spieser, the MIC at that time, was not present during normal business hours; and

b) The thermometer used for transfilling O_2 had not been calibrated, as requested on the February 10, 2009 inspection.

10. Community Medical Equipment's conduct, as stipulated to in paragraphs 8 and 9, violates 20 CSR 2220-5.030(2)(E), which states in pertinent part:

> (E) Drug distributor operations must be conducted at all times under the supervision of a properly designated manager-in-charge. The manager-in-charge must be actively involved and aware of the actual daily operations of the drug distributor operation. The manager-in-charge must be

> physically present at the drug distributor operation during normal business hours, except for time periods when absent due to illness, scheduled vacation or other authorized absence. . . .

11. Community Medical Equipment's conduct, as stipulated to in paragraphs 8 and 9, violates 20 CSR 2220-5.030(3)(M), which states in pertinent part:

> (M) Wholesale drug and pharmacy distributors shall establish, maintain and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory and distribution of prescription drugs, including policies and procedures for identifying, recording and reporting losses or thefts and for correcting all errors and inaccuracies in inventories . . . .

12. Community Medical Equipment's conduct, as stipulated to in paragraphs 8 and 9, violates 20 CSR 2220-5.030(1), which states in pertinent part:

> (1) Drug distributors must maintain standards of practice that will ensure that only drugs of appropriate quality will be distributed to practitioners for further compounding and dispensing to the public. These standards shall be subject to periodic reviews through the board's inspection process.

13. Community Medical Equipment's conduct, as stipulated to in paragraphs 8 and 9, violates 20 CSR 2220-5.070(4), which states in pertinent part:

> (4) A medical gas distributor that is involved in the manufacture/transfilling of medical gases must register with the Food and Drug Administration (FDA) as a medical gas manufacturer and comply with the drug listing requirements of the federal act. In addition, all current good manufacturing practice requirements as set forth in 21 CFR 210 through 211 must be complied with.

14. Community Medical Equipment's conduct, as stipulated to in paragraphs 8 and 9, violates 21 CFR § 211.22(a) and (d), which state in pertinent part:

> (a) There shall be a quality control unit that shall have the responsibility and authority to approve or reject all components, drug product containers, closures, in-process materials, packaging material, labeling, and drug products, and the authority to review production records to assure that no errors have occurred or, if errors have occurred, that they have been fully investigated. The quality control unit shall be responsible for approving or rejecting drug products manufactured, processed, packed, or held under contract by another company.
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> . . . .
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> (d) The responsibilities and procedures applicable to the quality control unit shall be in writing; such written procedures shall be followed.

15. Community Medical Equipment's conduct, as stipulated to in paragraphs 8 and 9, violates 21 CFR § 211.68(a), which states in pertinent part:

> (a) Automatic, mechanical, or electronic equipment or other types of equipment, including computers, or related systems that will perform a function satisfactorily, may be used in the manufacture, processing, packing, and holding of a drug product. If such equipment is so used, it shall be routinely calibrated, inspected, or checked according to a written program designed to assure proper performance. Written records of those calibration checks and inspections shall be maintained.

16. Community Medical Equipment's conduct, as stipulated to in paragraphs 8 and 9, constitutes incompetency, misconduct, and gross negligence in the performance of its functions or duties, which provides cause to discipline its wholesale drug distributor license pursuant to § 338.055.2(5), RSMo.

17. Community Medical Equipment's conduct, as stipulated to in paragraphs 8 and 9, violates the rules and regulations adopted pursuant to Chapter 338, RSMo, which

provides cause to discipline its wholesale drug distributor license pursuant to § 338.055.2(6), RSMo.

18. Community Medical Equipment's conduct, as stipulated to in paragraphs 8 and 9, violates its clients' professional trust and confidence, which provides cause to discipline its wholesale drug distributor license pursuant to § 338.055.2(13), RSMo.

19. Community Medical Equipment's acts and omissions, as stipulated to in paragraphs 8 and 9, causes it to be in violation of the drug laws and regulations of this state and the federal government, which provides cause to discipline its wholesale drug distributor license pursuant to § 338.055.2(15), RSMo.

II.
Joint Agreed Disciplinary Order

Based on the foregoing, the parties mutually agree and stipulate that the following shall constitute the disciplinary order entered by the Board in this matter under the authority of § 536.060, RSMo, and §§ 621.045.3 and 621.110, RSMo, Cum. Supp. 2010.

20. **Community Medical Equipment's license is on probation.** Community Medical Equipment's license as a drug distributor, no. 2004013278, is hereby placed on **PROBATION** for a period of **TWO (2) YEARS**. The period of probation shall constitute the "disciplinary period." During the disciplinary period, Community Medical Equipment shall be entitled to practice as a drug distributor under Chapter 338, RSMo, as amended, provided Community Medical Equipment adheres to all the terms of this agreement.

21. **Terms and conditions of the disciplinary period.** The terms and conditions of the disciplinary period are as follows:

(A) Community Medical Equipment shall pay all required fees for licensing to the Board and shall renew its drug distributor license prior to October 31 of each licensing year.

(B) Community Medical Equipment shall comply with all provisions of Chapters 338 and 195, RSMo, as amended, and all applicable federal and state drug laws, rules and regulations and with all federal and state criminal laws. "State" here includes the State of Missouri and all other states and territories of the United States.

(C) If, after disciplinary sanctions have been imposed, Community Medical Equipment fails to keep its drug distributor license current, the period of unlicensed status shall not be deemed or taken as any part of the time of discipline so imposed.

(D) Community Medical Equipment shall report to the Board, on a preprinted form supplied by the Board office, once every 6 months (due by each January 1 and July 1), beginning with whichever date occurs first after this Agreement becomes effective, stating truthfully whether or not it has complied with all terms and conditions of this disciplinary order.

(E) Community Medical Equipment shall select an independent consultant for the purpose of reviewing and insuring all compliance measures are carried out in accordance with all applicable laws and regulations. Community Medical Equipment shall submit documentation and credentials of its chosen consultant to the Board office for approval prior to the beginning date of probation. Said consultant shall submit a

written plan to the Board's office outlining what procedures or changes in operation will be implemented and on what time table is proposed for completion. The consultant shall then provide ongoing reports to the Board office attesting to the drug distributor's compliance or noting deficiencies for each visit made. The visits and initial reports shall be provided within sixty (60) days of the beginning of probation. Visits to the drug distributor to assess compliance will be completed at a minimum of a six (6) month cycle and reports to the Board office will be provided once every six (6) months throughout the disciplinary period. The consultant shall be hired at Community Medical Equipment's expense.

(F) Community Medical Equipment shall make a representative of the drug distributor available for personal interviews to be conducted by a member of the Board or the Board of Drug distributor staff. Said meetings will be at the Board's discretion and may occur periodically during the disciplinary period. Community Medical Equipment will be notified and given sufficient time to arrange these meetings.

22. Community Medical Equipment's failure to comply with any condition of discipline set forth herein constitutes a violation of this Settlement Agreement.

23. Upon the expiration of the disciplinary period, the license of Community Medical Equipment shall be fully restored if all requirements of law have been satisfied; provided, however, that in the event the Board determines that Community Medical Equipment has violated any term or condition of this Settlement Agreement, the Board may, in its discretion, after an evidentiary hearing, vacate and set aside the discipline

imposed herein and may suspend, revoke or otherwise lawfully discipline Community Medical Equipment's license.

24. No additional discipline shall be imposed by the Board pursuant to the preceding paragraph of this Settlement Agreement without notice and opportunity for hearing before the Board as a contested case in accordance with the provisions of Chapter 536, RSMo, as amended.

25. This Settlement Agreement does not bind the Board or restrict the remedies available to it concerning any future violations by Community Medical Equipment of Chapter 338, RSMo, as amended, or the regulations promulgated thereunder, or of the terms and conditions of this Settlement Agreement.

26. This Settlement Agreement does not bind the Board or restrict the remedies available to it concerning facts or conduct not specifically mentioned in this Settlement Agreement that are either now known to the Board or may be discovered.

27. If any alleged violation of this Settlement Agreement occurred during the disciplinary period, the parties agree that the Board may choose to conduct a hearing before it either during the disciplinary period, or as soon thereafter as a hearing can be held, to determine whether a violation occurred and, if so, may impose further disciplinary action. Community Medical Equipment agrees and stipulates that the Board has continuing jurisdiction to hold a hearing to determine if a violation of this Settlement Agreement has occurred.

28. Each party agrees to pay all their own fees and expenses incurred as a result of this case, its litigation, and/or its settlement.

29. The terms of this Settlement Agreement are contractual, legally enforceable, and binding, not merely recital. Except as otherwise contained herein, neither this Settlement Agreement nor any of its provisions may be changed, waived, discharged, or terminated, except by an instrument in writing signed by the party against whom the enforcement of the change, waiver, discharge, or termination is sought.

30. The parties to this Settlement Agreement understand that the Board will maintain this Settlement Agreement as an open record of the Board as required by Chapters 324, 338 and 610, RSMo, as amended.

31. Community Medical Equipment, together with its partners, shareholders, officers, directors, heirs, assigns, agents, employees, representatives and attorneys, does hereby waive, release, acquit and forever discharge the Board, its respective members, employees, agents and attorneys including former members, employees, agents and attorneys, of, or from any liability, claim, actions, causes of action, fees, costs, expenses and compensation, including, but not limited to, any claim for attorney's fees and expenses, whether or not now known or contemplated, including, but not limited to, any claims pursuant to § 536.087, RSMo, as amended, or any claim arising under 42 U.S.C. § 1983, which now or in the future may be based upon, arise out of, or relate to any of the matters raised in this case or its litigation or from the negotiation or execution of this Settlement Agreement. The parties acknowledge that this paragraph is severable from the remaining portions of the Settlement Agreement in that it survives in perpetuity even in the event that any court or administrative tribunal deems this agreement or any portion thereof void or unenforceable.

32. Community Medical Equipment understands that it may, either at the time the Settlement Agreement is signed by all parties, or within fifteen (15) days thereafter, submit the agreement to the Administrative Hearing Commission for determination that the facts agreed to by the parties constitute grounds for disciplining Community Medical Equipment's license. If Community Medical Equipment desires the Administrative Hearing Commission to review this Settlement Agreement, Community Medical Equipment may submit its request to: Administrative Hearing Commission, Truman State Office Building, Room 640, 301 W. High Street, P.O. Box 1557, Jefferson City, Missouri 65102.

33. If Community Medical Equipment requests review, this Settlement Agreement shall become effective on the date the Administrative Hearing Commission issues its order finding that the Settlement Agreement sets forth cause for disciplining Community Medical Equipment's license. If the Administrative Hearing Commission issues an order stating that the Settlement Agreement does not set forth cause for discipline, then the Board may proceed to seek discipline against Community Medical Equipment as allowed by law. If Community Medical Equipment does not request review by the Administrative Hearing Commission, the Settlement Agreement goes into effect fifteen (15) days after the document is signed by the Executive Director of the Board.

LICENSEE

CHARITION HELATH SYSTEMS, INC., d/b/a COMMUNITY MEDICAL EQUIPMENT

Authorized Representative of Licensee

By signing below, I hereby certify that:
1) I am an owner, partner, corporate officer/director, or manager-in-charge of this license and;
2) I am authorized to sign this settlement on the Licensee's behalf.

Sign: _____

Print: Greg Speiser

Title: Owner/CEO

Date: 10-5-11

VAN MATRE, HARRISON, HOLLIS, AND TAYLOR, P.C.

_____

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